
Development of OSSM-007, cryopreserved interferon-gamma primed allogeneic MSCs, for treatment of steroid refractory acute graft versus host disease

Grant Award Details

Development of OSSM-007, cryopreserved interferon-gamma primed allogeneic MSCs, for treatment of steroid refractory acute graft versus host disease

Grant Type: Late Stage Preclinical Projects

Grant Number: CLIN1-14070

Investigator:

Name:	Brian Johnstone
Institution:	Ossium Health
Type:	PI

Award Value: \$3,457,858

Status: Pre-Active

Grant Application Details

Application Title: Development of OSSM-007, cryopreserved interferon-gamma primed allogeneic MSCs, for treatment of steroid refractory acute graft versus host disease

Public Abstract:**Therapeutic Candidate or Device**

OSSM007: cryopreserved, interferon-gamma-primed bone marrow mesenchymal stem cells (BM-MSCs)

Indication

acute Graft versus host disease (aGVHD) resulting from hematopoietic cell transplantation

Therapeutic Mechanism

Immunomodulation of host-reactive T cells to induce operational tolerance of donor HSC-derived lymphocytes through direct cell-to-cell contact and secreted paracrine factors. Interferon-gamma priming of MSCs enhances therapeutic effects through establishing the cells in a immunosuppressive state prior to treatment. Primed cells are able to quickly activate regulatory T cells as well as direct suppress host-reactive T cell activity.

Unmet Medical Need

Systemic steroid therapy is the standard first-line treatment for aGVHD; however, the disease becomes refractory to systemic steroid therapy in 35–50% of patients. Mortality rates for patients who fail to respond to first-line steroid therapy are 80% due to very limited alternative treatments.

Project Objective

Commence Phase 1 clinical trial

Major Proposed Activities

- Address clinical hold CMC issues, including OSSM-007 manufacturing reproducibility and stability of product
- Develop a matrix of predictive potency assays and demonstrate utility in a mouse aGVHD model
- Refine the clinical dosing regimen by conducting a dose escalation study in a humanized mouse model of aGVHD

Statement of Benefit to California:

Steroid-refractory acute Graft-versus-host-disease (SR-aGVHD) is a severe health concern given the 80% mortality rate associated with the disease. There are no effective treatments currently available, thus, SR-aGVHD patients face a very poor prognosis. Development of OSSM-007 has the potential to extend the lifespans of this patient population by reducing disease severity and, potentially, reversing the course of the disease.

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